50161/KMO/W112

ULTRASOUND ABLATION CATHETER AND METHOD FOR ITS USE

BACKGROUND

Standard radio frequency (RF) ablation, performed using one or more electrode elements, is not very successful for epicardial ablation because it is not directional. RF ablation creates a lesion that burns the tissue in all directions, thereby burning the pericardium. As the burned pericardium heals, it tends to adhere to the epicardial tissue. Further, the lesions created using RF ablation are too shallow to be effective. Thus, a need exists for a catheter that is particularly effective for epicardial ablation.

SUMMARY OF THE INVENTION

The invention is directed to catheters and methods for epicardial ablation using ultrasound energy. In one embodiment, the invention is directed to a catheter that is particularly useful for epicardial ablation. The catheter comprises an elongated catheter body having proximal and distal ends. An ultrasound transducer is mounted at or near the distal end of the catheter body. The transducer has a front surface and an opposing back surface. The transducer is positioned to transmit ultrasound energy toward tissue facing the front surface but not toward tissue facing the back surface. A sensor is mounted within the catheter body near the ultrasound transducer for sensing a location and an orientation of the ultrasound transducer within a patient. With this catheter, the operator can easily determine the precise location and orientation of the ultrasound transducer to assure that the ablation energy is reaching the tissue to be treated.

In another embodiment, the invention is directed to a catheter comprising an elongated catheter body having proximal and distal ends. A tip electrode is mounted at the distal end of the catheter body. The tip electrode has

an exposed electrode surface and a transducer mounting surface opposite the exposed electrode surface. An ultrasound transducer is mounted on the transducer mounting surface of the tip electrode.

In yet another embodiment, the invention is directed to a catheter comprising an elongated catheter body having proximal and distal ends. An ultrasound transducer mounted at or near the distal end of the catheter body. The transducer has a front surface and an opposing back surface,. The transducer is positioned to transmit ultrasound energy toward tissue facing the front surface but not toward tissue facing the back surface. A control handle is mounted at the proximal end of the catheter body. A deflection wire extends through the catheter body. The deflection wire has a distal end fixedly attached near the catheter body's distal end and a proximal end anchored to a mechanism in the control handle that facilitates longitudinal movement of the deflection wire relative to the catheter body. The deflection wire is anchored at a position that is about 70° to 120° relative to the direction that energy is emitted from the transducer to thereby deflect the distal end of the catheter in a direction generally transverse to the direction that energy is emitted from the transducer.

In still another embodiment, the invention is directed to a method for epicardial ablation in a patient. The method comprises introducing into the pericardium of a patient a distal end of a catheter comprising an elongated tubular body with a transducer mounted at or near the distal end of the tubular body. The transducer has a front surface and an opposing back surface. The transducer is positioned to transmit ultrasound energy toward tissue facing the front surface but not toward tissue facing the back surface. The transducer's front surface is positioned so that it generally faces tissue to be ablated. The tissue to be ablated is then ablated with ultrasound energy generated by the transducer.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side view of an embodiment of the catheter of the invention.

FIG. 2 is a side cross-sectional view of a catheter body according to the invention, including the junction between the proximal shaft and distal shaft.

FIG. 3 is a perspective view of a transducer mounted on a tip electrode according to the invention.

FIG. 4 is a side view of a tip electrode according to the invention, with the holes and passages within the tip electrode shown in phantom.

FIG. 5 is an end cross-sectional view of the tip electrode of FIG. 4 along line 5-5.

FIG. 6 is an end cross-sectional view of the tip electrode of FIG. 4 along line 6-6.

FIG. 7 is an end cross-sectional view of a tip electrode of the invention, including the cable, tube and wires extending into the tip electrode.

FIG. 8 is a side cross-sectional view of the distal end of a catheter according to the invention showing that extend within the exposed section of the tip electrode.

FIG. 9 is an enlarged view of the thermocouple wires mounted in the tip electrode of FIG. 8.

FIG. 10 is an end cross-sectional view of the tubing of the distal shaft shown in FIG. 8 along line 10-10.

DETAILED DESCRIPTION.

As shown in FIG. 1, the catheter comprises an elongated catheter body **10** including a proximal shaft **12** and a distal shaft **14** and a control handle **16** at the proximal end of the proximal shaft.

With reference to FIG. 2, the proximal shaft **12** comprises an elongated tubular construction having a single, axial or central lumen **18**. The proximal shaft **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The proximal shaft **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **22** made of a polyurethane or nylon. The outer wall **22** comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body **10** so that, when the control handle **16** is rotated, the distal shaft **14** will rotate in a corresponding manner.

The outer diameter of the proximal shaft **12** is not critical, but is preferably no more than about 8 french, more preferably no greater than about 7 french. Likewise the thickness of the outer wall **22** is not critical. If desired, the inner surface of the outer wall **22** may be lined with a stiffening tube (not tube), which, along with the braided outer wall **22**, can provide improved torsional stability while at the same time minimizing the wall thickness of the catheter, thus maximizing the diameter of the central lumen **18**. An catheter including a stiffening tube is described in more detail in U.S. Patent No. 6,203,507, the disclosure of which is incorporated herein by reference.

In the depicted embodiment, the distal shaft **14** comprises a short section of flexible tubing **19** having three lumens, a puller wire lumen **30**, an irrigation lumen **32**, and a cable and wire lumen **34**. The tubing **19** is made of a suitable non-toxic material that is preferably more flexible than the proximal shaft **12**. A presently preferred material for the tubing **19** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like, that

is more flexible than the catheter body. The number and size of the lumens is not critical and can vary depending on the various wires, tubes and other components carried by the catheter. In a preferred embodiment, the distal shaft **14** has an outer diameter ranging from about 5 french (.066 inch) to 8 french (.105 inch).

One means for attaching the proximal shaft **12** to the distal shaft **14** is illustrated in FIG. 2. The proximal end of the distal shaft **14** comprises an outer circumferential notch **24** that receives the inner surface of the outer wall **22** of the proximal shaft **12**. The distal shaft **14** and proximal shaft **12** are attached by glue or the like. Other arrangements for joining the proximal and distal shafts are considered within the scope of the invention. For example, the proximal and distal shafts can be made from a single tubing so that the proximal and distal shafts include the same number of lumens. Alternatively, if a stiffening tube is provided, the stiffening tube can extend slightly beyond the distal end of the proximal shaft **12** (e.g., about 3 mm) and be glued to the proximal shaft, with the proximal end of the distal shaft **14** cored out to receive the distal end of the stiffening tube, creating a lap joint. The lap joint and the butt joint formed between the distal end of the proximal shaft **12** and the proximal end of the distal shaft **14** can be secured with polyurethane glue or the like. In another alternative, the proximal shaft **12** can be thermally fused to the distal shaft **14.**

If desired, a spacer (not shown) can be located within the proximal shaft **12** at its distal end, adjacent the proximal end of the distal shaft **14**. The spacer provides a transition in flexibility at the junction of the proximal shaft and distal shaft, which allows this junction to bend smoothly without folding or kinking. A catheter having such a spacer is described in U.S. Patent No. 5,964,757, the disclosure of which is incorporated herein by reference.

At the distal end of the distal shaft **14** is a tip electrode **36**. As shown in FIGs. 3 and 4, the tip electrode **36** has an exposed section **37** having a length

ranging preferably from about 2 mm to about 10 mm, more preferably from about 6 mm to about 8 mm, and a stem **39** having a diameter less than the diameter of the exposed section and having a length ranging preferably from about 1 mm to about 6 mm, more preferably from about 2 mm to about 4 mm.

The exposed section **37** of the tip electrode **36** includes an ultrasound transducer **38** mounted thereon. In the depicted embodiment, the exposed section **37** of the tip electrode **36** has an outer ablation surface **40** that is generally co-linear with the outer surface of the tubing **19** and generally rounded like the outer surface of the tubing. The exposed section **37** also includes a cut-out region to provide a transducer surface **42** on which the transducer **38** is mounted. Preferably the cut-out region is sufficiently deep so that, when the transducer **38** is mounted on the transducer surface **42**, the transducer does not extend beyond the outer circumference of the tubing **19**.

In the depicted embodiment, the transducer **38** comprises three generally-rectangular and generally-flat layers. The central layer **44** is a generally rectangular plate comprising a piezoceramic or piezoelectric crystalline material. The central layer **44** preferably is made of a type PZT-4, PZT-5 or PZT-8, quartz or Lithium-Niobate type piezoceramic material to ensure high power output capabilities. These types of transducer materials are commercially available from Stavely Sensors, Inc. (East Hartford, Connecticut) and from Valpey-Fischer Corp. (Hopkinton, Massachusetts). The outer and inner layers **43** and **45** enclose the central layer **44** and are each constructed of an electrically conductive material, thereby forming transducer electrodes. These outer and inner transducer layers **43** and **45** may each comprise a metallic coating, such as a coating of nickel, copper, silver, gold, platinum, or an alloy thereof. The inner transducer layer **45** can be mounted onto the tip electrode **36** in any suitable manner, for example, by soldering the inner transducer layer to the transducer surface **42** of the tip electrode.

The length of the transducer **38** is selected for a given clinical application and is desirably not longer than the length of the exposed section **37** of the tip electrode **36**. The transducer **38** length preferably ranges from about 2 mm to about 10 mm, more preferably from about 5 mm to about 10 mm. The central layer **44** of the transducer **38** has a thickness selected to produce a desired operating frequency. The operating frequency will vary depending upon clinical needs, such as the depth of heating, as well as upon the size of the transducer as limited by the delivery path and the size of the target site. The transducer **38** in the illustrated embodiment preferably operates at a frequency ranging from about 5 MHz to about 20 MHz, and more preferably from about 7 MHz to about 10 MHz. Thus, for example, the transducer can have a thickness of approximately 0.3 mm for an operating frequency of about 7 MHz (i.e., a thickness generally equal to 1/2 the wavelength associated with the desired operating frequency).

The piezoelectric crystal that forms the central layer **44** of the ultrasound transducer **38** is adapted to contract and expand (or "vibrate") when an alternating current is applied from a current source and across the outer and inner layers **43** and **45**. This controlled vibration emits the ultrasonic energy direction away from and generally perpendicular to the generally flat surfaces of the outer and inner layers **43** and **45** to thereby ablate tissue. However, because the inner layer **45** is facing the transducer surface **42** of the tip electrode **36**, the energy emitted from the inner layer **45** does not ablate tissue. As a result, ablation can be controlled by directing the ultrasound energy in one direction, i.e., away from the flat surface of the outer layer **43**.

The transducer **38** preferably is "air-backed" to produce more energy and to enhance energy distribution uniformity, as is known in the art. In other words, the inner transducer layer **45** does not contact an appreciable amount of the transducer surface **42** of the tip electrode **36**. As best shown in FIGs. 5 and

6, the transducer surface **42** of the tip electrode **36** is slightly concave, and the inner transducer layer **45** is generally flat. The bottom edges **46** of the inner transducer layer **45** are soldered to the transducer surface **42**, thereby leaving an air-gap between the central region of the inner transducer layer and the transducer surface. The sides and the proximal and distal ends of the transducer **38** are then sealed, for example, with epoxy or a silicone glue (not shown), which is a good sealant and resistant to high temperatures. When the sides and the ends of the transducer **38** are sealed, air is trapped in the air-gap between the transducer and the transducer surface **42** of the tip electrode **36**. The air in the air-gap reflects the ultrasound energy directed toward the tip electrode **36** so that the ultrasound energy reverses direction, providing more energy in the desired direction, i.e., toward the tissue to be ablated.

For applying an alternating current from a current source across the outer and inner layers **43** and **45**, electrical transducer leads are electrically coupled to outer and inner layers of the transducer **38** by any suitable method. In the depicted embodiment, a coaxial cable **48** is provided, which includes a coaxial center and a coaxial shield. The coaxial center is connected to the outer transducer layer **43** with a coaxial center wire **51** by solder or the like. The coaxial shield **52** is connected to the inner transducer layer **45** by soldering a coaxial shield wire **53** to the coaxial shield and to the tip electrode **36**, which, as noted above, is attached to the inner transducer layer. The proximal ends of the coaxial center and coaxial shield of the coaxial cable **48** are adapted to couple to an appropriate ultrasound or radiofrequency generator (not shown).

The coaxial cable **48** extends through the central lumen **18** of the proximal shaft **12** and through the cable and wire lumen **34** of the distal shaft **14**. The coaxial center wire **51** extends through a wire passage **54** in the tip electrode **36**. As best shown in FIG. 4, the wire passage **54**, which extends through the stem **39** and a part of the exposed section **37** of the tip electrode, is on the side of

the tip electrode including the cut-out, i.e., the side on which the transducer **38** is mounted. The coaxial shield wire **53** that connects the coaxial shield to the tip electrode **36** extends into a first blind hole **56** in the tip electrode and is soldered within the first blind hole. Other arrangements for the transducer wires are within the scope of the invention.

A radiofrequency (RF) generator (not shown) introduces electrical current to the transducer **36**, which converts the electrical current into ultrasonic pressure waves. Alternatively, An ultrasonic generator can be used to generate alternating current to power the transducer **36**. The ultrasonic generator drives the transducer at frequencies ranging from about 5 to about 20 MHz, and preferably for the illustrated application ranging from about 7 MHz to about 10 MHz. In addition, the ultrasonic generator can modulate the driving frequencies and/or vary power to smooth or unify the produced collimated ultrasonic beam. For instance, the function generator of the ultrasonic generator can drive the transducer at frequencies ranging from about 6.8 MHz to about 7.2 MHz by continuously or discretely sweeping between these frequencies.

With this design, the transducer **38** has a front surface, i.e., the surface of the outer layer **43** farthest from the transducer surface **42** of the tip electrode **36**, and an opposing back surface, i.e., the surface of the inner layer **45** nearest the transducer surface of the tip electrode. The tip electrode **36** prevents the transducer **38** from transmitting ultrasound energy toward tissue facing the back surface, so that the transducer is positioned to transmit ultrasound energy toward only the tissue facing the front surface. The transducer **38** is preferably generally flat, as depicted in FIG. 3, but could be slightly curved if desired. If desired, the transducer **38** can be mounted on the distal shaft **14** instead of on the tip electrode **36**.

The tip electrode **36** is connected to the distal shaft tubing **19** by means of a generally rigid tubular plastic housing **21**, preferably made of polyether-

etherketone (PEEK). The stem **39** of the tip electrode **36** fits inside the distal end of the plastic housing **21** and is bonded to the housing by polyurethane glue or the like. The proximal end of the plastic housing **21** is bonded with polyurethane glue or the like to the distal end of the tubing **19** of the distal shaft **14**. It is understood that the tip electrode alternatively may be connected directly to the tubing **19** of the distal shaft**14** as desired as is well known in the art. If desired, the transducer **38** can be mounted on the plastic housing **21** instead of on the tip electrode **36**.

In the embodiment shown, a ring electrode **58** is mounted on the distal end of the plastic housing **21**. The ring electrode **58** is slid over the plastic housing **21** and fixed in place by glue or the like. If desired, additional ring electrodes may be used and can be positioned over the plastic housing **21** or over the flexible tubing **19** of the distal shaft **14**.

The tip electrode **36** and ring electrode **58** are each connected to a separate lead wire **60**. The lead wires **60** extend through the plastic housing **21**, the cable and wire lumen **34** of the distal shaft **14**, the central lumen **18** of the proximal shaft **12**, and the control handle **16**, and each terminates at its proximal end in an input jack **29** that may be plugged into an appropriate monitor (not shown) and/or source of radio frequency or other ablation energy (not shown). If desired, the portion of the lead wires **60** extending through the proximal shaft **12** and control handle **16** may be enclosed or bundled within a protective tube **26**.

The lead wire **60** for the tip electrode **36** is anchored in the first blind hole **56** of the tip electrode by solder or the like. Any other means for electrically-connecting the lead wire **60** to the tip electrode **36** may also be used.

A lead wire **60** is attached to the ring electrode **58** by any conventional technique. Connection of a lead wire **60** to the ring electrode **58** is preferably accomplished by first making a small hole through the plastic housing **21**. Such a hole can be created, for example, by inserting a needle through the plastic

housing **21** and heating the needle sufficiently to form a permanent hole. A lead wire **60** is then drawn through the hole by using a microhook or the like. The ends of the lead wire **60** are then stripped of any coating and soldered or welded to the underside of the ring electrode **58**, which is then slid into position over the hole and fixed in place with polyurethane glue or the like.

A temperature sensor is provided for the tip electrode **36** and, if desired, the ring electrode **58**. Any conventional temperature sensor, e.g., a thermocouple or thermistor, may be used. A preferred temperature sensor for the tip electrode **36** comprises a thermocouple formed by an enameled wire pair. One wire of the wire pair is a copper wire **62**, e.g., a number 40 copper wire. The other wire of the wire pair is a constantan wire **64**. The wires **62** and **64** of the wire pair are electrically isolated from each other except at their distal ends where they are twisted together, covered with a short piece of plastic tubing **66**, e.g., polyimide, and covered with epoxy. The plastic tubing **66** is then mounted in a second blind hole **57** in the tip electrode **36**, and held in place by polyurethane glue or the like. Alternatively, the wires **62** and **64** can be soldered into the second blind hole **57**. In another alternative embodiment, the copper wire **62** of the thermocouple can also be used as a lead wire for the tip electrode **36**.

The thermocouple wires **62** and **64** extend through the cable and wire lumen **34** in the distal shaft **14** and through the central lumen **18** of the proximal shaft **12**. The wires **62** and **64** then extend out through the control handle **16** and to a connector (not shown) connectable to a temperature monitor (not shown).

An infusion tube **28** is provided for introducing fluid, such as saline, to the tip electrode **36**. The infusion tube **28** is preferably made of a biocompatible plastic, such as polyimide. The infusion tube **28** has a distal end anchored in an irrigation passage **65** in the tip electrode **36**. In the depicted embodiment, the

irrigation passage **65** extends through the stem **39**and into exposed section **37** generally parallel to the axis of the tip electrode **36**, but does not extend out the distal end of the tip electrode. Three irrigation branches **67** extend radially from the irrigation passage **65**, as best shown in FIG. 6. Irrigation or cooling fluid can be introduced from the infusion tube **28** into the irrigation passage **65** so that the fluid can pass out of the tip electrode **36** through the irrigation branches **67** to thereby cool and/or irrigate the region being ablated.

The infusion tube **28** extends through the irrigation lumen **32** of the distal shaft **14**, through the proximal shaft **12**, out the proximal end of the control handle **16**, and terminates in a luer hub **49** or the like at a location proximal to the control handle. In an alternative arrangement, a single lumen side arm (not shown) is fluidly connected to the central lumen **18** near the proximal end of the catheter body **10**, as described in more detail in U.S. Patent No. 6,120,476, the entire disclosure of which is incorporated herein by reference. Alternatively, the infusion tube **28** can terminate within the distal end of the irrigation lumen **32** of the distal shaft **14**, with a second infusion tube (not shown) extending from the proximal end of the infusion lumen, through the proximal shaft **12** and out through the control handle **16**. Such a design is also described in more detail in U.S. Patent No. 6,120,476.

A puller wire **68** (or deflection wire) is provided within the catheter for deflecting the distal shaft **14**. The puller wire **68** is anchored at its proximal end to the control handle **16** and anchored at its distal end to the distal shaft **14**. The puller wire **68** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire **68**. The puller wire **68** preferably has a diameter ranging from about 0.006 to about 0.010 inches.

A compression coil **70** is situated with the proximal shaft **12** in surrounding relation to the puller wire **68**. The compression coil **70** extends from

the proximal end of the proximal shaft **12** to the proximal end of the distal shaft **14**. The compression coil **70** is made of any suitable metal, preferably stainless steel. The compression coil **70** is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil **70** is preferably slightly larger than the diameter of the puller wire **68**. For example, when the puller wire **68** has a diameter of about 0.007 inches, the compression coil **70** preferably has an inner diameter of about 0.008 inches. The Teflon® coating on the puller wire **68** allows it to slide freely within the compression coil **70**. Along its length, the outer surface of the compression coil **70** is covered by a flexible, non-conductive sheath **72** to prevent contact between the compression coil **70** and the lead wires **60** within the proximal shaft **12**. A non-conductive sheath **72** made of polyimide tubing is presently preferred.

The compression coil **70** is anchored at its proximal end to the proximal end of the proximal shaft **12** by proximal glue joint **74** and at its distal end to the distal shaft **14** by distal glue joint **76**. Both glue joints **74** and **76** preferably comprise polyurethane glue or the like. The puller wire **68** extends into the puller wire lumen **30** of the distal shaft **14**. The puller wire **68** is anchored in the first blind hole **56** of the tip electrode **36**. In the depicted embodiment, the puller wire lumen **30** and the first blind hole **56** are arranged at an angle of about 70° to about 120°, more preferably about 90°, relative to the direction that energy is emitted from the transducer **38** to thereby deflect the distal end of the catheter in a direction generally transverse to, and preferably generally perpendicular to, the direction that energy is emitted from the transducer.

Preferably, a ferrule **69**, made of stainless steel or the like, is crimped onto the distal end of the puller wire **68** to add thickness to the puller wire. The ferrule **69** is then attached to the inside of the first blind hole **56** of the tip electrode **36** with solder or the like. Alternatively, the puller wire **68** can be

anchored to the side of the distal shaft **14**, as described in U.S. Patent No. 6,571,131, the disclosure of which is incorporated herein by reference. Within the distal shaft **14**, the puller wire **68** extends through into a plastic, preferably Teflon®, sheath **81**, which prevents the puller wire **42** from cutting into the wall of the distal shaft **14** when the distal shaft is deflected.

A location sensor **82** is contained within the distal end of the distal shaft **14** for sensing the position and orientation of the transducer **38**. In the depicted embodiment, the location sensor **82** is mounted primarily within the plastic housing **21**. The distal end of the location sensor **82** extends into a trepanned region **84** in the proximal end of the stem **39** of the tip electrode **36**. Depending on the length of the location sensor **82**, its proximal end can extend into the tubing **19** of the distal shaft **14**. The location sensor **82** is fixed in place by polyurethane glue or the like. Alternatively, the location sensor **82** may be mounted proximal to the tip electrode **36**. Other arrangement for mounting the location sensor **82** near the tip electrode **36** (and thus near the transducer **38**) are within the scope of the invention. The location sensor **82** is mounted preferably within 10 mm, more preferably within 5 mm, of the transducer **38**. In a particularly preferred embodiment, the location sensor **82** is positioned directly under the transducer.

The location sensor **82** is connected to a sensor cable **84**, which extends through the cable and wire lumen **34** of the distal shaft **14**, through the proximal shaft **12** and into the control handle **16**. The sensor cable **84** comprises multiple wires encased within a plastic covered sheath. Within or outside the control handle **16**, the sensor cable **84** is connected to a circuit board (not shown). The circuit board amplifies the signal received from the location sensor **82** and transmits it to a computer in a form understandable by the computer. Because the catheter is designed for single use only, the circuit board may contain an EPROM chip that shuts down the circuit board approximately 24 hours after the

catheter has been used. This prevents the catheter, or at least the location sensor, from being used twice. A catheter having a control handle in which a circuit board is housed is described in U.S. Patent No. **[insert]**, the disclosure of which is incorporated herein by reference.

Preferably each location sensor **82** is an electromagnetic location sensor. For example, each location sensor **82** may comprise a magnetic-field-responsive coil, as described in U.S. Patent No. 5,391,199, or a plurality of such coils, as described in International Publication WO 96/05758. The plurality of coils enables the six-dimensional coordinates (i.e. the three positional and the three orientational coordinates) of the location sensor **80** to be determined. Alternatively, any suitable location sensor known in the art may be used, such as electrical, magnetic or acoustic sensors. Suitable location sensors for use with the present invention are also described, for example, in U.S. Patent Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, and 5,568,809, and International Publication Nos. WO 95/02995, WO 97/24983, and WO 98/29033, the disclosures of which are incorporated herein by reference.

Longitudinal movement of the puller wire **68** relative to the proximal shaft **12**, which results in deflection of the distal shaft **14**, is accomplished by manipulation of the control handle **16**. Examples of suitable control handles suitable for use in the present invention are disclosed, for example, in U.S. Patent Nos. Re 34,502 and 5,897,529, the entire disclosures of which are incorporated herein by reference.

If desired, two or more puller wires can be provided to enhance the ability to manipulate the distal shaft. In such an embodiment, a second puller wire and a surrounding second compression coil extend through the proximal shaft and into an additional off-axis lumen in the distal shaft. If desired, the first puller wire can be anchored proximal to the anchor location of the second puller wire. Suitable designs of catheters having two or more puller wires, including suitable

control handles for such embodiments, are described, for example, in U.S. Patent Nos. 6,123,699, 6,171,277, 6,183,435, 6,183,463, 6,198,974, 6,210,407, and 6,267,746, the disclosures of which are incorporated herein by reference.

In use, the catheter is introduced into a patient so that the distal end of the catheter is positioned in or around a patient's heart. The catheter is particularly suitable for epicardial ablation. With epicardial ablation, the distal end of the catheter is introduced into the pericardium by any suitable technique. Examples of techniques that can be used in connection with the present invention include those disclosed in U.S. Patent Nos. 6,161,543 and 6,314,963, the disclosures of which are incorporated herein by reference. The distal end is manipulated so that the transducer is generally facing the myocardial tissue. The directional nature of ultrasound energy, discussed above, makes it particularly suitable for ablating the myocardial tissue without also ablating the surrounding pericardial sack. Further, the deep-penetrating nature of the ultrasound energy makes it particularly suitable for burning deep lesions in the myocardial tissue.

Due to the directional nature of the ultrasound energy, it is highly desirable to be able to view the relative positions of the transducer **38** and the myocardial tissue to be ablated. The location sensor **82** permits this information to be easily determined. To use the location sensor **82**, the patient is placed in a magnetic field generated, for example, by placing a pad containing coils for generating a magnetic field under the patient. A reference electromagnetic sensor is fixed relative to the patient, e.g., taped to the patient's back, and the catheter containing a second electromagnetic sensor is advanced into the patient's heart. Each sensor comprises three small coils that, in the magnetic field, generate weak electrical signals indicative of their position in the magnetic field. Signals generated by both the fixed reference sensor and the second sensor in the heart are amplified and transmitted to a computer which analyzes the

signals and then displays the signals on a monitor. By this method, the precise location of the sensor in the catheter relative to the reference sensor can be ascertained and visually displayed.

Using this technology, the physician can visually map the pericardium or a heart chamber. This mapping is done by advancing the catheter tip into a heart chamber until contact is made with the heart wall. This position and electrograms are recorded and saved. The catheter tip is then moved to another position in contact with the heart wall and again the position is recorded and saved. This procedure is repeated until a three dimensional map of the heart chamber is achieved. The electromagnetic mapping sensor **82** preferably is used in combination with the tip electrode **36** and ring electrode **58**. By combining the electromagnetic sensor **82** and electrodes **36** and **58**, a physician can simultaneously map the contours or shape of the heart chamber and the electrical activity of the heart.

After such a map is created, the physician can position the catheter with the transducer **38** within the pericardium and use the location sensor **82** to determine and adjust the position and orientation of the transducer relative to the myocardial tissue to be ablated. The transducer **38** is then used to ablate a lesion in the myocardial tissue. The lesion preferably has a depth ranging from about 2 mm to about 5 mm. If desired, both the transducer **38** and tip electrode **36** can be used to ablate tissue. In such an instance, ablation with the tip electrode **36** can be performed before, during or after ablation with the transducer **38**.

Saline or other cooling or irrigation fluid can be passed through the irrigation branches **67** in the tip electrode **38** by introducing the fluid into the infusion tube **28** through the luer hub **49**. The use of cooling fluid to cool the tissue being ablated reduces or even eliminates burning and charring of the tissue. For example, optimal burns having a depth of 2 to 3 mm were formed at

5W/15 mL/min. Higher power was found to result in tissue charring and a superficial burn, as the ultrasound energy probably does not penetrate through the char.

As noted above, the puller wire lumen **30** and the first blind hole **56** are arranged at an angle of about 90° relative to the direction that energy is emitted from the transducer **38**. With this design, the transducer **38** is mounted parallel to the deflection plane so that, when the catheter is in the pericardium, deflecting it would make the catheter sit flat with the transducer pointing directly into the myocardium.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.